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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,628	06/27/2005	Augustinus Bader	Q-85446	3519

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

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07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,628	BADER, AUGUSTINUS	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/05;9/05;10/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 28 - 40 in the reply filed on April 13, 2007 is acknowledged.

Claims 41 – 52 are canceled. Claims 28 – 40 are pending and have been considered on the merits.

Claim Objections

2. Claims 31 – 33 and 36 – 40 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 28 – 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is indefinite for reciting "EFO" because the term has not been adequately defined by the claim language or specification.

In claims 28 and 40, term "where appropriate" renders the claims indefinite because it is unclear under what circumstances require the limitations that follow.

Claim 28 is indefinite for reciting "use of" in line 9, because it is unclear what use is being claimed.

Claim 29 and its dependents are drawn to a method for in vitro generation of tissue, however are rendered vague and indefinite because it is unclear what growth factors are in the alternative, and which are required to meet the limitation of the claims. For purposes of examination, each of the claimed GF have been interpreted as in the alternative.

In claims 29, 31 - 33, 37 and 38, the phrases "in particular" and "preferably" render the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 36 is indefinite for reciting "a transplant" because it is unclear what applicant intends to encompass by the term.

Claim 37 is rendered vague and indefinite for reciting "already prepared" because it is unclear what is "already prepared".

In claims 37 line 7, "the inductive remodeling" lacks sufficient antecedent basis.

Claim 39 is so confusing that it is unclear what is being claimed. It is unclear if the claims are to an intended use of the method of claim 29, or if the claim is further limiting claim 29, and if so, it is unclear in what manner.

Claim 40 is indefinite for reciting "a suitable device" because the phrase has not been adequately defined by the claim language or specification.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 28 – 30 and 32 – 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Naughton et al. (US 4963489).

Applicant claims a method for in vitro regeneration of tissue, the method comprising multiplying and differentiating cells by initiating, terminating and structurally guiding the cells with growth factors selected from TPO, EPO, GH, somatostatin, LIP and/or CNTF. The method further comprises employing TGF, beta, prostaglandin, GM-CSF, GHRH, TRH, GnRH, CRH, dopamine, ADH, oxytocin, prolactin, adrenocorticotropin, beta-celitropin, lutrotropin and/or vasopressin. The method is practiced wherein the endothelial cells are present; the growth of cells is locally initiated, terminated and structurally guided; growth is initiated, terminated and guided by a biological matrix or supporting structure. The biological matrix or structure is treated with one or more growth factors as a mixture or sequentially; an implant, transplant or supporting material is used as a biological matrix or support structure for cell growth; the biological matrix or support is precolonized with cells selected from tissue specific cells,

precursor cells, bonemarrow cells, peripheral blood cells, adipose tissue and/or fibrous tissue; or is previously prepared in vitro for in vivo colonization; and the cells are progenitor cells, tissue specific cells, osteoblasts, fibroblasts, hepatocytes, and/or smooth muscle cells. The method is practiced wherein a liver sectate is provided, administering EPO, TPO, GH, or derivatives thereof and using the treated sectate for treating liver disorders.

Naughton teaches methods for generating tissues comprising culturing cells and tissue in vitro wherein the cells proliferate into tissues (abstract) and wherein growth factors such as GH, somatomedins (somatostatin), EPO, and/or prostaglandins (col.12 line 14-27) are added to alter, modulate proliferation and/or differentiation (or the cells are multiplied, differentiated, initiated, terminated and structurally guided by growth factors) (col.12). The added cells may be endothelial cells (abstract), bone marrow cells, liver cells (col.3 line 26-36), fibroblasts, plasma cells (peripheral blood cells), adipocytes (adipose cells), mast cells (tissue specific cell) (col.3 line 45-50), smoot muscle cells, or osteoblasts (col.10). The growth of the cells are guided by a biological matrix which can be used as an implant or transplant material (col.25, abstract). Naughton teaches the cell aggregates are broken up (examples, col.29).

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 28 – 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton as evidenced by Chen et al. (US 5076492).

Applicant claims a method for in vitro regeneration of tissue, the method comprising multiplying and differentiating cells by initiating, terminating and structurally guiding the cells with growth factors selected from TPO, EPO, GH, somatostatin, LIP and/or CNTF. The method further comprises employing TGF, beta, prostaglandin, GM-CSF, GHRH, TRH, GnRH, CRH, dopamine, ADH, oxytocin, prolactin, adrenocorticotropin, beta-celitropin, lutrotropin and/or vasopressin; or nerve regeneration factors (NGF), vessel regeneration factors (VEGF), and/or PDGF. The method is practiced wherein the endothelial cells are present; the growth of cells is locally initiated, terminated and structurally guided; growth is initiated, terminated and guided by a biological matrix or supporting structure. The biological matrix or structure is treated with one or more growth factors as a mixture or sequentially; an implant, transplant or supporting material is used as a biological matrix or support structure for cell growth; the biological matrix or support is precolonized with cells selected from tissue specific cells, precursor cells, bone marrow cells, peripheral blood cells, adipose tissue and/or fibrous tissue; or is previously prepared in vitro for in vivo colonization; and the cells are progenitor cells, tissue specific cells, osteoblasts, fibroblasts, hepatocytes, and/or smooth muscle cells. The method is practiced wherein cell aggregates are broken up, encapsulated and frozen; or wherein a liver sectate is provided, administering EPO, TPO, GH, or derivatives thereof and using the treated sectate for treating liver disorders.

Naughton teaches methods for generating tissues comprising culturing cells and tissue in vitro wherein the cells proliferate into tissues (abstract) and wherein growth factors such as GH, somatomedins (somatostatin), EPO, and/or prostaglandins (col.12 line 14-27) are added to alter, modulate proliferation and/or differentiation (or the cells are multiplied, differentiated, initiated, terminated and structurally guided by growth factors) (col.12). The added cells may be endothelial cells (abstract), bone marrow cells, liver cells (col.3 line 26-36), fibroblasts, plasma cells (peripheral blood cells), adipocytes (adipose cells), mast cells (tissue specific cell) (col.3 line 45-50), smoot muscle cells, or osteoblasts (col.10). The growth of the cells are guided by a biological matrix which can be used as an implant or transplant material (col.25, abstract). Naughton teaches the cell aggregates are broken up (examples, col.29).

Naughton does not teach the method wherein all of the claimed growth factors are used in the method. However, at the time of the claimed invention, the instant growth factors were well known and used in the art to generate cells into tissues. In support, Chen teaches culturing endothelial cells in the presence of VEGF (abstract). Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use any of the claimed growth factors in the methods of Naughton as a matter of routine practice as evidenced by

Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice and Chen to use any of the claimed growth factors in the methods of Naughton with a reasonable expectation for successfully generating tissues in vitro.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner
Art Unit 1651

July 6, 2007